EXHIBIT O

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, FL

Appeal of:	**A. Prosser**	ALJ Appeal No.:	**1-8390277469**
Beneficiary:	**A. Prosser**	**Medicare Part B**	
HICN:	*****4857A**	Before:	**J. Grow** U.S. Administrative Law Judge

DECISION

After careful consideration of the entire record, an unfavorable decision is entered.

PROCEDURAL HISTORY

Claims were submitted to Medicare for an electrical stimulation device used for cancer treatment, HCPCS code E0766, dates of service 1/16/18, 2/16/18, 3/16/18, and 4/16/18. *See* Exh. 1 at 3. This type of treatment is also referred to as Tumor Treatment Field Therapy (TTFT). *Id.* These claims were denied, and Appellant filed an appeal which was denied upon redetermination and reconsideration. Exh. 1 at 13-16 and 1-7. At the reconsideration level, the Qualified Independent Contractor (QIC) listed the denial rationale as Local Coverage Determination L34823 (LCD L34823) requirements had not been met. Exh. 1 at 4. The QIC found the medical provider, and not the Appellant/Beneficiary (Appellant), liable for the non-covered charges. Exh. 1 at 5.

This matter involves a claim that meets the amount in controversy requirement, and the Appellant made a timely request for an Administrative Law Judge (ALJ) hearing before the Office of Medicare Hearings and Appeals (OMHA). *See* 42 C.F.R. § 405.1014(b)(1).

I held a telephone hearing on May 20, 2019. Debra M. Parrish, Esq., appeared for Appellant. Timothy Parks, Clinical Registered Nurse for the electrical stimulation device supplier, testified on Appellant's behalf. Exhibits 1 through 5 were admitted to the record without objection.

ISSUES

A. Whether Medicare covers the electrical stimulation device/treatment, and

B. If Medicare coverage is denied, then whether the waiver of liability provisions pursuant to § 1879 of the Social Security Act are applicable.

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual or an organization that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A) (42 U.S.C. § 1395ff(b)(1)(A)).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions the Medicare Appeals Council further review. *Id.*

In calendar year 2019, a hearing before an ALJ is only available if the remaining amount in controversy is $160 or more for requests filed. *See* 83 Fed. Reg. 47619 (Sep. 20, 2018). A party to a QIC reconsideration may request a hearing before an ALJ if the party files a written request for an ALJ hearing within 60 days after receipt of the notice of the QIC's reconsideration. 42 C.F.R. § 405.1002(a).

B. Scope of Review

The issues before the ALJ include all the issues from the initial, reconsidered or revised determination that were not decided entirely in the Appellant's favor; however, if evidence presented before or during the hearing causes the ALJ to question a fully favorable decision, the Appellant will be notified and it will be considered an issue at hearing. 42 C.F.R. § 405.1032(a).

The ALJ may decide a case on the record and not conduct an oral hearing if the evidence in the hearing record supports a finding in favor of Appellant on every issue, or if the Appellant and all parties indicate in writing that they do not wish to appear before the ALJ at oral hearing. 42 C.F.R. § 405.1038.

The burden of proving each element of a Medicare claim lies with the Appellant by a preponderance of the evidence. *See* 42 C.F.R. §§ 424.5(a)(6), 405.1018, 405.1028, and 405.1030. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJ's. 42 C.F.R. § 405.1063.

An Appellant may offer new evidence for the first time at the ALJ level of appeal only upon a showing of good cause why the evidence was not submitted to the QIC or a prior decision maker. The ALJ will determine whether good cause exists for the late submission of the new evidence and may only consider the evidence in making a decision if good cause is found. *See* 42 C.F.R.

§§ 405.1018, 405.1028, and 405.1030. This new evidence restriction does not apply to unrepresented beneficiaries. *See* 42 C.F.R. § 405.1018(d).

Unless the ALJ dismisses the hearing request, the ALJ will issue a written decision that states findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d). *De novo* review requires the ALJ to review and evaluate the evidence without regard to the findings of prior determinations on the claim and make an independent assessment relying upon the evidence and controlling laws.

II. Applicable Law

The Medicare program, Title XVIII of the Act, is administered through CMS, a component of HHS. The Secretary of HHS is authorized to enter into contracts with private entities for the administration of Part B of Title XVIII, the Supplementary Medical Insurance program, which provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of specific health-related items and services. *See* Act § 1842(a).

Part B beneficiaries participate voluntarily in the Medicare Part B program and pay a monthly premium. Part B entitles a beneficiary to have payments made on his or her behalf for "medical and other health services." Act § 1861(s)(3).

The items and services that are "not reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are specifically excluded from Medicare coverage. Act § 1862(a)(1)(A). Further, payment to any provider of services is precluded unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." Act § 1833(e) of the Act; *see* 42 C.F.R. § 424.5(a)(6).

The Act limits the liability of the beneficiary and providers of services if the services are found to be not medically reasonable and necessary under Section 1862(a)(1) of the Act or care was custodial in nature under Section 1862(a)(9) of the Act, and neither the beneficiary nor the provider knew or could reasonably have been expected to know that the services were not covered. Act § 1879; 42 U.S.C. § 1395pp; *see* 42 C.F.R. §§ 411.404, 411.406.

Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of

medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs). Act § 1871(a)(2)

The Act provides that ALJs will give substantial deference to LCDs, LMRPs or CMS program guidance when applicable, and if they do not follow the policy they must explain why in their decision. Act § Section 1869(f)(2); *see also* 42 CFR § 405.1062.

Specific to the instant case is Local Coverage Determination L34823, LCD for Tumor Treatment Field Therapy (effective 10/01/15), which was promulgated by CGS Administrators, LLC. It provides, in part: Tumor treatment field therapy (E0766) will be denied as not reasonable necessary.

The Medicare Appeals Council has cited LCD L34823 on several occasions in determining no Medicare TTFT coverage exists. *See* Medicare Appeals Council docket numbers M-19-1231 (April 23, 2019); M-19-755 (March 14, 2019); M-19-525 (March 14, 2019); and M-19-453 (March 8, 2019). Although these Council decisions are not precedential, they nonetheless represent HHS's final decision.

FINDINGS OF FACT AND ANALYSIS

1. *Medicare does not cover the electrical stimulation device/treatment at issue because LCD L34823, which was in effect during the dates of service at issue, indicated there was no Medicare coverage for this device/treatment, and I must give LCDs substantial deference.*

The Appellant's attorney, Ms. Parrish, submitted a prehearing brief which discussed medical literature and professional medical societies which have determined that TTFT is safe and efficient. Exh. 4 at 6-7. Ms. Parrish's brief also discussed clinical trials which have shown TTFT to be safe and efficient. Ms. Parrish also emphasized in her brief that TTFT has been widely accepted by many major United States health coverage payors, as well as the fact that the Centers for Medicare Services previously assigned a HCPCS code with regard to TTFT devices. Exh. 4 at 8-8A. Finally, Ms. Parrish argued in her brief that LCD L34823 should not be given substantial deference due to several factors, including: "…the LCD's obvious failure to reflect the peer-reviewed literature, consensus of experts, and acceptance by the relevant medical community…." Exh. 4 at 8A.

At the hearing, Ms. Parrish emphasized that the Appellant was considered a "newly diagnosed" glioblastoma patient as of the dates of service at issue which were in 2016. She also discussed a favorable OMHA ALJ decision which had recently been issued with regard to different dates of service involving this same issue and this same Appellant. Ms. Parrish also indicated that medical contractors had proposed a new policy on May 9, 2019 which would allow Medicare TTFT coverage for newly diagnosed glioblastoma patients. According to Ms. Parrish, this had been preceded by a Medicare carrier advisory meeting which took place in early March 2019, following which the participants had recommended TTFT Medicare coverage for newly diagnosed glioblastoma patients. She also discussed a new proposed LCD which would provide TTFT coverage for newly diagnosed glioblastoma patients. According to Ms. Parrish, this new proposed LCD was in the public comment process as of the hearing date, May 20, 2019. Ms.

Parrish requested that I grant coverage for the Appellant here either by giving the current LCD substantial deference but refraining from applying the LCD or by taking the position that the evidence shows that the current LCD should only apply to "recurrent" glioblastoma patients and not to newly diagnosed glioblastoma patients.

Mr. Parks testified at the hearing regarding the Appellant's clinical presentation and the various treatment modalities she had undergone since being diagnosed. He also discussed the differences between "newly diagnosed" glioblastoma and "recurrent" gliobastoma.

Although I find the Appellant's arguments compelling, I also find the Appellant's arguments amount to challenges to the underlying record upon which the LCD is based. A separate adjudicative process is available for aggrieved parties to challenge whether that LCD record is complete and adequate to support the validity of the LCD. *See* 42 C.F.R. 426.25 and Part 426 generally. I cannot make those types of findings here because I do not have the record upon which the LCD is based before me.

Given that LCD L34823 was in effect during the dates of service at issue and continues to remain in effect at the present time, I must substantially defer to the LCD and find no coverage.

2. *The provider, and not the Appellant, is responsible for the non-covered charges.*

The Act limits the liability of the Beneficiary and providers of items and services if the items and services are found to be not medically reasonable and necessary under Section 1862(a)(1) of the Act or care was custodial in nature under Section 1862(a)(9) of the Act, and neither the Beneficiary nor the provider knew or could reasonably have been expected to know that the items and services were not covered. Act § 1879; 42 U.S.C. § 1395pp; *see* 42 C.F.R. §§ 411.404, 411.406.

Medicare can reimburse for non-covered items and services if the provider or supplier of the items and services does not know, or have reason to know, that Medicare does not cover the items and services. The provider is a Medicare participant and must comply with all applicable laws and regulations. As a Medicare participant, the provider should be familiar with Medicare laws, regulations, and policies. The provider should have known the device and services that it provided to the Appellant are not covered by Medicare. The provider is therefore responsible for the non-covered charges.

The individual receiving the items and services is not liable for payment to the provider if the individual does not know, or have reason to know, that Medicare does not cover the items and services. There is no evidence in the record here indicating Appellant received advance notice, or knew, or should have known, that Medicare did not cover the item and service. Appellant is therefore not responsible for the non-covered charges.

CONCLUSIONS OF LAW AND ORDER

Medicare does not cover the item and services the Appellant received on the dates of service at issue. The Appellant is not liable to the provider for the item and services. The provider is not

eligible for coverage under § 1879 of the Act or Medicare regulations.

The Medicare contractor will process Appellant's claim in accordance with this decision.

Dated: JUN 19 2019

J. Grow
U.S. Administrative Law Judge